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## VIA UPS NEXT DAY AIR

Dr. Robert Moore
Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

July 9, 2004

JUL 1 3 2004

Re: Fulfillment of Reporting Obligation Under 21 U.S.C. § 343 (r) and 21 C.F.R. § 101.93

Dear Dr. Moore:

Whole World Botanicals, Inc. , ¹ by counsel and in accordance with 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Whole World Botanicals retains scientific documentation supporting the statements.

## 1. Supplement Brand Name

Royal Camu

## Ingredients

Camu Camu (Dehydrated Fruit on maltodextrin).

## Text of Statements of Nutritional Support

A natural food source of Vitamin C.

Extensive research on Vitamin C, of which Camu Camu is a natural source, suggests that Camu Camu standardized to 8% Vitamin C promotes a healthy immune system and supports mood balance.

Scientific research documents the effects of V itamin C to promote a healthy immune system. Camu Camu, a superior food source of V itamin C, has been noted clinically to have these effects.

Scientific research suggests that Vitamin C taken as a dietary supplement supports mood balance by affecting serotonin metabolism. Camu Camu, as a natural food source of Vitamin C, has been noted clinically to promote mood balance.

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In accordance with 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93 (c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

Respectfully submitted,

Vien Muller

Viana Muller, PhD.

President